

IN THE CLAIMS

Please cancel claims 30-31 without prejudice, add new claims 32-57, and amend as follows:

1. (Currently Amended) A method of preparing a sustained release formulation of a peptide or peptidomimetic, which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the peptide suspended at a concentration of at least 25 mg/mL without formation of a gel, such that, when administered to a subject, the peptide is released in vivo over a period of at least two weeks.
2. (Original) The method of claim 1, wherein the counter-ion is a trifluoromethanesulfonic acid, benzenesulfonic acid, trifluoroacetic acid or sulfuric acid.
3. (Currently Amended) The method of claim 1, wherein ~~in which~~ the counter-ion is a strong acid and the peptide is a GnRH analogue.
4. (Currently Amended) The method of claim 3, wherein ~~in which~~ the GnRH analogue is a GnRH antagonist.
5. (Currently Amended) The method of claim 4, wherein ~~in which~~ the GnRH antagonist is Ac—D—Nal—DCpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂.
6. (Currently Amended) The method of claim 4, wherein ~~in which~~ the GnRH antagonist is Azaline B, Abarelix, Antide, Ganirelix, Cetrorelix, or FE200486 and is in the form of a an alkylsulfonate, arylsulfonate, trifluoroacetate or sulfate salt.
7. (Currently Amended) The method of claim 1, wherein ~~in which~~ the peptide is a somatostatin analogue.

8. (Currently Amended) The method of claim 1, wherein ~~in which~~ the somatostatin analogue is Vapreotide, Octreotide, Lanreotide, or SOM 230.

9. (Currently Amended) The method of claim 1, wherein the peptide or peptidomimetic forms a salt with the counter-ion, and the salt is suspended in the aqueous medium at a concentration of at least 25 mg/[[ml]]mL.

10. (Currently Amended) The method of claim 9, wherein ~~in which~~ the aqueous suspension is injected parenterally into a mammal or human subject to obtain a sustained release of the peptide or peptidomimetic over at least one month.

11. (Currently Amended) The method of claim 9, wherein ~~in which~~ the amount of peptide or peptidomimetic in the suspension to be injected ranges from about 0.1 to 5 mg per kg body weight of the mammal or human subject.

12. (Currently Amended) A fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic and a counter-ion of a strong proton donor in water, wherein the peptide or peptidomimetic and counter-ion are present in amounts and at a molar ratio sufficient to form the suspension of the peptide at a concentration of at least 25 mg/mL ~~peptide or peptidomimetic~~ upon mixing without formation of a gel.

13. (Original) The suspension of claim 12, wherein the counter-ion is trifluoromethanesulfonic acid, benzenesulfonic acid, trifluoroacetic acid, or sulfuric acid.

14. (Currently Amended) The suspension of claim 12, wherein ~~in which~~ the counter-ion is a strong acid and the peptide is a GnRH analogue.

15. (Currently Amended) The suspension of claim 14, wherein ~~in which~~ the GnRH analogue is a GnRH antagonist.

16. (Currently Amended) The suspension of claim 14, wherein ~~in which~~ the GnRH antagonist is Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂.

17. (Currently Amended) The suspension of claim 14, wherein ~~in which~~ the GnRH antagonist is Azaline B, Abarelix, Antide, Ganirelix, Cetrorelix, or FE200486 and is in the form of a an alkylsulfonate, arylsulfonate, trifluoroacetate or sulfate salt.

18. (Currently Amended) The suspension of claim 12, wherein ~~in which~~ the peptide is a somatostatin analogue.

19. (Currently Amended) The suspension of claim 18, wherein ~~in which~~ the somatostatin analogue is Vapreotide, Octreotide, Lanreotide or SOM 230.

20. (Currently Amended) The suspension of claim 12, wherein the peptide or peptidomimetic forms a salt with the counter-ion, and the salt is suspended in the aqueous medium at a concentration of equal to or higher than 25 mg/[[ml]]mL.

21. (Currently Amended) The suspension of claim 12, wherein ~~in which~~ the aqueous suspension contains an isotonic agent.

22. (Currently Amended) The suspension of claim 21, wherein ~~in which~~ the isotonic agent is mannitol.

23. (Original) The suspension of claim 12, which further comprises a pharmaceutically acceptable excipient.

24. (Currently Amended) The suspension of claim 23, wherein ~~in which~~ the amount of peptide or peptidomimetic ranges from about 0.1 to 5 mg per kg body weight of a mammal or human to which the suspension is to be administered.

25. (Currently Amended) The suspension of claim 12, wherein the peptide is at least partially in the form of microcrystals having a particle size of between about 1 and 150 μm .

26. (Currently Amended) A lyophilized composition comprising ~~the a~~ dried suspension of claim 12.

27. (Previously Presented) A method of making the lyophilized composition of claim 26 which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide the suspension without formation of a gel, and lyophilizing the suspension to obtain the composition.

28. (Previously Presented) A method of preparing a fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic which comprises adding water or a buffer solution to the lyophilized composition of claim 26 with mixing to obtain the suspension.

29. (Currently Amended) A method of preparing a fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio with the peptide that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the peptide or peptidomimetic at a concentration of at least 25 mg/mL without formation of a gel; lyophilizing the suspension to form a lyophilized composition; and adding water or a buffer solution to the lyophilized composition with mixing to obtain the suspension.

30. (Cancelled)

31. (Cancelled)

32. (New) A fluid, milky microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·trifluoroacetate.

33. (New) The suspension of claim 32, which provides, when administered to a subject, a sustained release of peptide in vivo.

34. (New) The suspension of claim 33, wherein the sustained release is over a period of two weeks.

35. (New) The suspension of claim 32, wherein Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·trifluoroacetate is suspended in an aqueous medium at a concentration of equal to or greater than 25 mg/mL.

36. (New) The suspension of claim 32, further comprising an isotonic agent.

37. (New) The suspension of claim 36, wherein the isotonic agent is mannitol.

38. (New) The suspension of claim 32, further comprising a pharmaceutically acceptable excipient.

39. (New) The suspension of claim 32, wherein microcrystals are in the form of needles having a particle size of between 1 and 150 μm.

40. (New) A method of preparing the suspension of claim 32 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂ with trifluoroacetate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel.

41. (New) A method of preparing a lyophilized composition comprising Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·trifluoroacetate comprising, lyophilizing the suspension of claim 32.

42. (New) A lyophilized composition comprising a dried suspension obtained by the method of claim 41.

43. (New) A method of preparing a microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·trifluoroacetate comprising, adding water or buffer with mixing to the lyophilized composition of claim 42.

44. (New) A method of preparing the suspension of claim 32 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂ with trifluoroacetate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel; lyophilizing to form a lyophilized composition; and adding water or buffer with mixing.

45. (New) A fluid, milky microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·sulfate.

46. (New) The suspension of claim 45, which provides, when administered to a subject, a sustained release of peptide in vivo.

47. (New) The suspension of claim 46, wherein the sustained release is over a period of two weeks.

48. (New) The suspension of claim 45, wherein the Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·sulfate is suspended in an aqueous medium at a concentration of equal to or greater than 25 mg/mL.

49. (New) The suspension of claim 45, further comprising an isotonic agent.

50. (New) The suspension of claim 49, wherein the isotonic agent is mannitol.

51. (New) The suspension of claim 45, further comprising a pharmaceutically acceptable excipient.

52. (New) The suspension of claim 45, wherein microcrystals are in the form of needles having a particle size of between 1 and 150 µm.

53. (New) A method of preparing the suspension of claim 45 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂ with sulfate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel.

54. (New) A method of preparing a lyophilized composition comprising Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·sulfate comprising, lyophilizing the suspension of claim 45.

55. (New) A lyophilized composition comprising a dried suspension obtained by the method of claim 54.

56. (New) A method of preparing a microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂·sulfate comprising, adding water or buffer with mixing to the lyophilized composition of claim 55.

57. (New) A method of preparing the suspension of claim 45 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂ with the sulfate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel; lyophilizing to form a lyophilized composition; and adding water or buffer with mixing.